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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,391	01/08/2002	Eiji Shiojiri	215409US0	9970

22850 7590 07/06/2005

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/926,391

Applicant(s)

SHIOJIRI ET AL.

Examiner

Chih-Min Kam

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-19 and 24-41 is/are rejected.
- 7) ☒ Claim(s) 3 and 20-23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1 and 3-41 are pending.

Applicants' amendment filed April 22, 2005 is acknowledged. Applicant's response has been fully considered. Claims 1 and 24 have been amended. Therefore, claims 1 and 3-41 are examined.

Withdrawn Claim Rejections - 35 USC § 102

2. The previous rejection of claims 24-26, 30-33 and 38-41 under 35 U.S.C.102(b) as being anticipated by Janecka *et al.* (J. Med. Chem. 38, 2922-2924 (1995)), is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 16-17 in the amendment filed April 22, 2005.
3. The previous rejection of claims 1, 4, 8-11 and 16-19 under 35 U.S.C.102(e) as being anticipated by Baudoin *et al.* (U. S. Patent 5,861,529), is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 16-17 in the amendment filed April 22, 2005.
4. The previous rejection of claims 1 and 24 under 35 U.S.C.102(e) as being anticipated by Fukuda *et al.* (U. S. Patent 6,162,828, 102 (e) date, May 20, 1996), is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 16-17 in the amendment filed April 22, 2005.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 4-19 and 24-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 4-19 and 24-41 are directed to a compound having a naphthyl group and represented by Formula (1), which includes an amino acid compound (when $n=0$ and $m=0$ in claim 1, or $n=1$, $m=0$ in claim 24), a dipeptide (when $n=0$, $m=1$ in claim 1, or $n=1$, $m=0$ in claim 24), and a tripeptide (when $n=1$, $m=1$ in claim 24); a melanocyte-stimulating hormone (MSH) inhibitory composition, a whitening agent, an immunofunction controlling agent, an appetite controlling agent, or a cosmetic or external preparation for the skin comprising the compound of Formula (1) as the active ingredient. While the specification indicates that the invention provides di- or tri-peptide derivatives with the Formula (1) having a naphthyl group, which can inhibit the action of melanocyte-stimulating hormone, thereby the compound can be used as an active ingredient in a melanocyte-stimulating hormone inhibitory composition, a whitening agent, an immunofunction controlling agent, an appetite controlling agent, or a cosmetic preparation (pages 3-6), the specification does not disclose a genus of variants for the compounds of Formula (1) having inhibitory activity against MSH and their use as an active ingredient in a MSH inhibitory composition, a whitening agent, an immunofunction controlling agent, an appetite controlling agent, or a cosmetic preparation.

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The specification only discloses specific compounds of Formula (1) such as D-1-Nal-Arg-LeuNH₂, D-2-Nal-Arg-LeuNH₂, L-1-Nal-Arg-LeuNH₂, and L-2-Nal-Arg-LeuNH₂ have inhibitory activity against MSH (test Examples 1 and 4), and suppress the melanin formation (text Example 2), it does not describe how to identify an active amino acid, a dipeptide or a tripeptide compound among numerous compounds of Formula (1), nor discloses any particular structure to function/activity relationship in the compounds of formula (1). Furthermore, the specification does not disclose a genus of variants for functional compounds of formula (1). The skilled artisan cannot envision all the contemplated compounds of formula (1) having inhibitory activity against MSH based upon four specific naphthyl-tripeptides. Without guidance on structure to function/activity for the compounds of formula (1), one skilled in the art would not know which amino acids, dipeptides or tripeptides in compounds of formula (1) are essential for function/activity, and how to identify a functional compound. The lack of a structure to function/activity relationship in the compounds of formula (1), and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

New Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 1 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Iwama *et al.* (U.S. Patent 3,619,196).

Iwama *et al* teach the preparation of 1-hydroxy-2-naphthoyl-glycine, 1-hydroxy-2-naphthoyl- α -alanine and 1-hydroxy-2-naphthoyl- β -alanine by reacting phenyl-1-hydroxy-2-naphthoate with the corresponding amino acid in the basic condition (column 4, lines 44-69). For example, 1-hydroxy-2-naphthoyl- α -alanine which corresponds to the compound of formula (1), where Ar is 1-naphthyl substituted with hydroxyl group, n is 0, R² and R³ each is H, R⁴ is alanine side chain, X² is single bond, X³ is OH, m is 0, and R⁹ is H (claim 1). Since three different naphthoyl amino acids have been prepared by the same method, it would be obvious that other naphthoyl-amino acid compounds of Formula (I) can be prepared using the same procedure.

7. Claim 24 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Isler (U.S. Patent 2,179,979).

Isler teaches the preparation of 1-naphthylacetyl-leucine by reacting α -naphthyl-acetyl chloride with leucine under alkaline condition (whole page), which corresponds to the compound of formula (1), where Ar is 1-naphthyl, n is 1, X¹ is single bond, R¹, R⁶, R² and R³ are each H, R⁴ is leucine side chain, X² is single bond, X³ is OH, m is 0, and R⁹ is H (claim 24); Since three different 1-naphthylacetyl amino acids (e.g., leucine, glycine and sarcosine) have been prepared by the same method, it would be obvious that other naphthylacetyl-amino acid compounds of Formula (I) can be prepared using the same procedure.

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Claim Objections

8. Claims 3 and 20-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. Claims 1, 4-19 and 24-41 are rejected, and claims 3 and 20-23 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



**CHIH-MIN KAM
PATENT EXAMINER**

CMK

July 1, 2005